



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Doddabele L. Madhavi, *et al.*
Serial No. : 10/735,335
Filed: : December 12, 2003
For: : Bioavailable Carotenoid-Cyclodextrin Formulations For
Soft-Gels And Other Encapsulation Systems
TC/AU : 1623
Examiner : Matthew L. Fedowitz
Attorney Docket No. : BIO 2-016

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DECLARATION UNDER C.F.R. § 1.132

Doddabele Madhavi, Ph.D. and Daniel I. Kagan, Ph.D., do declare and state that:

1. Dr. Madhavi received a Bachelor of Science degree in Biology and Chemistry in 1977 from University of Mysore, Mysore, India; a Master of Science degree in Botony in 1979 from Mysore, Mysore, India, Majors: Plant Biochemistry, Physiology, and Genetics; and a Doctorate degree (Ph.D.) in Biochemistry in 1987 from Central Food Technological Research Institute, Mysore, India, Thesis : Studies on the effects of processing on amino acid availability and functional properties of vegetable proteins.
2. Dr. Madhavi was a Research Fellow at the Department of Protein Technology, Central Food Technological Research Institute, Research Focus: Physico-chemical properties of vegetable proteins. Mysore, India, '80 to '87; a Research Scientist at the Department of Fruit and Vegetable Technology, Central Food Technological Research Institute. Research focus: Phytochemicals in cell cultures of food crops. Mysore, India, '88 to '90; a Research Associate at the Department of Nutrition and Food Sciences, Utah State University. Research focus: Color stability in bovine skeletal muscles. Logan, UT, '91 to '93; a Research Associate at the Departments of Food Science and Horticulture, University of Illinois, Research focus: the presence and use of flavonoids in crop plants and cell cultures. Urbana, IL , '93 to '96; a Visiting Assistant Professor at the Department of Natural Resources and Environmental Sciences, University of Illinois, where she researched the screening, extraction and formulation of bioactive compounds from novel sources. Urbana, IL, '96 to 98; Chief Scientist for PhytoLife Sciences, Inc. where she

provided a mid-course evaluation of a novel technology to produce natural product for a company in a turn-around situation. With management, developed enhancements and alternatives to the technology to meet pressing needs to generate revenues. Succeeded in redirecting the Company's conceptual basis while still maintaining its core value. Responsible for all laboratory functions Columbus, OH, '98 to '99; and currently is Managing Partner for BioActives LLC, the assignee of the above-identified application where she provides the scientific expertise for new product development, process development and scientific/experimental strategies therein. In collaboration with management chart the company's strategic direction. Responsible for all laboratory functions including but not limited to the concept, experimental design and execution, ordering equipment and supplies, and personnel and environmental safety. Worcester, MA. Oct. '99 to present.

3. A more complete resume for Dr. Madhavi is attached hereto.
4. Dr. Kagan received a Bachelor of Science degree In Mathematics in 1963 from Worcester Polytechnic Institute, Worcester, MA; a Master of Arts degree in Psychology in 1972 from University of Colorado, Boulder, CO; Business Graduate Courses - M.B.A. Program -- University of Colorado (1973-74), completed 75% of MBA courses; and a Doctor of Philosophy in 1995 in Business/Entrepreneurial Studies from Union Institute, Cincinnati, OH.
5. Dr. Kagan was a Assistant Personnel Director for the City of Boulder, CO (1970-1979); built, managed, and supervised a vertically-integrated winter recreation company in Vermont (1979-1989); provided consulting and counseling services to small businesses (1989-1996); Chief Operating Officer for The American Mental Health Alliance (1995-1997); Chief Executive Officer, PhytoLife Sciences, botanical biotechnology company (1997-1999); and currently is a Managing Partner, BioActives LLC, a seed-stage biotechnology company that develops bioactive ingredients for the pharmaceutical, nutraceutical, and cosmeceutical industries, where his responsibilities include strategic planning, policy development, alliance building, and investor relations (1999-present).
6. A more complete resume for Dr. Kagan is attached hereto.
7. They both are co-inventors of and co-applicants for the invention described and claimed in the above-identified application.
8. They both are co-inventors of and co-applicants for the invention described and claimed in the copending application serial number 10/309,999, as represented by publication number 20040109920 (hereinafter, "USSN '999").

9. In USSN '999, Examples 1-3 directed to complexation of lutein with cyclodextrins was their sole concept.
10. In USSN '999, Examples 4-6 directed to preparation of coated carotenoid/cyclodextrin complexes was their sole concept and was needed because the complex was unstable as a powder.
11. In USSN '999, Examples 7-10 directed to using a polymer to coat the complex was the sole concept of Helmet Reuscher.
12. In USSN '999, Examples 11-12 directed to the stability of coated carotenoid/cyclodextrin complexes was their sole concept and the bioavailability data was only *in vitro* data conducted with carotenoid/cyclodextrin complex powder, as there were no human studies.
13. In USSN '999, spray drying was the only drying method studied and actually reduced to practice.
14. At the time the invention in USSN '999 was made, they had no idea that the method of drying would affect the recovery and bioavailability of the carotenoid/cyclodextrin complexes.
15. They were solely responsible for experimentally trying different drying techniques and discovering unexpectedly that a freeze-dried complex would be highly bioavailable and much more bioavailable than other forms of drying, especially spray drying, as disclosed and claimed in the above-identified patent application.
16. Thus, any disclosed but unclaimed subject matter in USSN '999, other than polymer coating agents, was solely the joint disclosure of them, inasmuch as the sole contribution of Helmet Reuscher was the polymer coating agents.
17. All statements made herein of their own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing therefrom.

FURTHER DECLARANTS SAYETH NAUGHT.

Date 4/26/05

D.L. Madhavi
Doddabele Madhavi, Ph.D.

Date 4/20/05

Daniel I. Kagan PhD
Daniel I. Kagan, Ph.D.